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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,675	03/23/2001	James R. Matson	067062.0110	5775

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PATENT DEPARTMENT
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EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 05/21/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/815,675

Applicant(s)
Matson

Examiner
John Kim

Art Unit
1723



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 4, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-12 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

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1. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,287,516 (Matson et al). Matson et al teach a hemofiltration system comprising a 100 kilo dalton to 150 kilo dalton hemofilter (102) to remove selective inflammatory mediators including TNF, IL-1 beta from blood and connected to an adsorptive device (108) having adsorbents including biological agent including anti-TNF antibody and monoclonal antibodies to remove inflammatory mediators (see figure 1; col. 5, line 17-23; col. 11, line 7 - col. 14, line 2).

2. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al as applied to claim 1 above, and further in view of U.S. Patent No. 6,008,199 (Grinnell et al '199). Claim 4 essentially differs from the hemofiltration system of Matson et al in reciting the provision of one pharmaceutical agent including activated protein C. Grinnell et al '199 teach that activated protein C is used to treat sepsis caused by inflammatory mediators because of its anti-inflammatory effects through its inhibition of cytokine generation (e.g. TNF and IL-1) (see abstract; col. 1, lines 41-53). It would have been obvious to a person of ordinary skill in the art to modify the hemofiltration system of Matson et al to provide one pharmaceutical agent including activated protein C to more effectively treat sepsis caused by inflammatory mediators as suggested by Grinnell et al '199.

3. Claim 5-6, 8-10, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al in view of U.S. Patent No. 6,008,199 (Grinnell et al '199). Matson et al teach a hemofiltration system and method comprising the step of receiving blood from a patient and filtering blood using a 100 kilo dalton to 150 kilo dalton hemofilter (102) to remove selective

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inflammatory mediators including TNF, IL-1 beta from blood and connecting an adsorptive device (108) having adsorbents including biological agent including anti-TNF antibody and monoclonal antibodies to remove inflammatory mediators to a hemofilter (see figure 1; col. 5, line 17-23; col. 11, line 7 - col. 14, line 2). Claims 5-6, 8-10 and 12 essentially differ from the hemofiltration system and method of Matson et al in reciting the step of providing a biological agent including activated protein C to blood. Grinnell et al '199 teach that activated protein C is infused to a patient's blood veins to treat sepsis caused by inflammatory mediators because of its anti-inflammatory effects through its inhibition of cytokine generation (e.g. TNF and IL-1) (see abstract; col. 1, lines 41-53). It would have been obvious to a person of ordinary skill in the art to modify the hemofiltration system and method of Matson et al to provide one biological agent including activated protein C into the blood to more effectively treat sepsis caused by inflammatory mediators as suggested by Grinnell et al '199.

4. Claims 1, 2, 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,193,681 (Davidner et al) in view of Grinnell et al '199. Davidner et al teach a hemofiltration system comprising a hemofilter (106) to remove selective inflammatory mediators including TNF, IL-1 beta from blood and connected to filter devices (111, 112) to remove inflammatory mediators including endotoxins (see col. 3, lines 8-36; col. 4, line 66 - col. 5, line 62; col. 7, lines 8-30). Davidner et al further teach that his hemofilter removes the inflammatory mediators including TNF, IL-1 beta that are removed by hemofilter of 100 kD - 150 kD of U.S. Patent No. 5,571,418 (Lee et al). Claims 1-2, 4 and 11 essentially differ from the hemofiltration

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system of Davidner et al in reciting the provision of one pharmaceutical agent including activated protein C. Grinnell et al '199 teach that activated protein C is used to treat sepsis caused by inflammatory mediators because of its anti-inflammatory effects through its inhibition of cytokine generation (e.g. TNF and IL-1) (see abstract; col. 1, lines 41-53). It would have been obvious to a person of ordinary skill in the art to modify the hemofiltration system of Davidner et al to provide one pharmaceutical agent including activated protein C to more effectively treat sepsis caused by inflammatory mediators as suggested by Grinnell et al '199.

5. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a therapeutic agent **provided to the filtered blood**) are not recited in the rejected claims 1-12. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.


When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

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John Kim
Primary Examiner
Art Unit 1723

J. Kim
April 28, 2003